UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,399	10/28/2003	Robert Ivkov	134848.01301	6391

21269 7590 03/25/2010

PEPPER HAMILTON LLP
ONE MELLON CENTER, 50TH FLOOR
500 GRANT STREET
PITTSBURGH, PA 15219

EXAMINER	
LAURITZEN, AMANDA L	
ART UNIT	**PAPER NUMBER**
3737	

MAIL DATE	DELIVERY MODE
03/25/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/696,399	IVKOV ET AL.	
	Examiner	Art Unit	
	Amanda L. Lauritzen	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 111-114* is/are pending in the application.

4a) Of the above claim(s) *18-110* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 111-114* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to communications filed 11 December 2009. Amendments to the claims are not interpreted to introduce new matter. The terminal disclaimer included in that submission is sufficient to overcome the outstanding double patenting rejection with respect to US 6,997,863 and US 7,074,175. The provisional double patenting rejection(s) are repeated herein as appropriate until allowable subject matter is indicated in either the present application or the conflicting applications.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11 December 2009 has been entered.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive and/or are moot in view of new grounds of rejection.

Applicant has amended to specify that the susceptor includes a magnetic particle, a biocompatible coating and a ligand, wherein the ligand enables association of the susceptor with disease material. Examiner concedes that the references to Gray et al. and Itoh et al. do not teach

these feature(s), but an additional reference to Gruettner et al. is presented to address the amendment(s).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1, 2, 3 and 8-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7-10, 13-16, 41, 42, 45 and 49-51, 53-59, 62 and 72-74 of copending Application No. 11/258,598. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets are directed to a thermotherapeutic system (or complementary method) requiring an alternating magnetic field, common details of a magnetic circuit, common details of a coil, common details of circular rotar (or rotating pair) of magnets to generate a magnetic flux, etc,

with the instant claims being broader and therefore anticipated by the conflicting claims. The instant claims are broader in that they do not detail a specific frequency range for the AMF, nor do they prescribe a shape of the waveform.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 19-23 of copending Application No. 10/493,874. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets are directed to a thermotherapeutic system (or complementary method) prescribing an alternating magnetic field and associated inductor, with the instant claim(s) being broader and therefore anticipated by the conflicting claims. The instant claims are broader in that they do not detail a specific frequency range for the AMF.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 2, 12-15, 16, 17, 18 and 111-114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray et al. (US 6,167,313) in view of Itoh et al. (US 4,979,518) and Gruettner et al. (US 2005/0271745).

Gray et al. disclose a bioprobe in the form of a temperature probe for use in a thermotherapy disease treatment including a susceptor in the form of a microcapsule suspension that is to be injected into the arterial blood supply of diseased tissue (col. 1, lines 22-34 for hyperthermia of cancerous cells; col. 4, line 43 for a temperature probe; also col. 9, lines 44-47 for the susceptor injector probe). The system includes an alternating magnetic field inducing inductor that produces an alternating magnetic field that will act to energize the injected material (col. 3, lines 1-15). The alternating magnetic field inductor is understood to include some generator or power source.

Gray et al disclose all features of the invention as substantially claimed, as detailed above, but the susceptor material is injected and is not specifically associated with the probe; however, Itoh et al teach a bioprobe for use with a hyperthermal system that includes a susceptor on the probe in the form of an iron oxide powder and a metallic acid salt (abstract; also col. 11, lines 14-15). It would have been obvious to one of ordinary skill in the art at the time of invention to include a probe that comprises a susceptor as taught by Itoh et al for the purpose of generating a heat reaction in the probe at the site of the susceptor upon exposure to the alternating magnetic field.

The combination of Gray et al. and Itoh et al. includes all features of the invention as substantially claimed, as detailed above, but does not specifically include a ligand to enable association of the susceptor with disease material; however, in the same field of invention Gruettner et al. teach biocompatible magnetic particle compositions, in conjunction with ligands, that enable selective attachment of the associated bioprobe or susceptor for targeting of disease markers on cells, as in [0074]. It would have been obvious to one of ordinary skill in the

relevant art at the time of invention to provide a ligand physically linked with the susceptor or bioprobe for associating with disease tissue, as taught in Gruettner et al., with the combination of Gray and Itoh et al., in order to target or mark biological areas within the patient.

It is noted that the probes disclosed are susceptors to the extent that they are magnetic, metallic and responsive to the magnetic field to the extent that it absorbs electromagnetic energy (see, for example, Gray et al. at col. 4, lines 28-46). The metallic acid salt of the probe of Itoh et al. also constitutes a susceptor. Additionally, providing a susceptor as a bioprobe subject to an alternating magnetic field is obvious within the skill of the art.

Regarding claims 111-114, the method of Gray et al. is specific to obtaining of a temperature measure, such that progress can be monitored in raising a temperature of a sample above a given threshold (col. 1, lines 22-34).

During treatment, Gray et al specifies that patients are subject to a magnetic field with a desired strength and frequency (col. 5, lines 11-16). Since the patient is disclosed to be within the apparatus, it is understood that the poles of the magnet define a patient-receiving gap, as in claim 2.

Regarding claims 12-15, Gray cites use of antibodies in targeting cancerous cells. Known antibodies for use include those derivatives according to claim 14, 15.

Regarding claims 17 and 18, the system of Gray et al includes one or more bioprobes, the first being in the form of a temperature probe and the second being in the form of an injecting probe, which are understood to be distinct from one another.

4. Claims 3, 4, 8, 9, 10, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray et al. (US 6,167,313) in view of Itoh et al. (US 4,979,518) and Gruettner et al., (US 2005/0271745), as applied to claims 1 and 2, further in view of Huang et al. (US 2005/0151438).

Gray et al as appended by the thermal probe of Itoh and Gruettner et al. includes all features of the invention as substantially claimed but does not specifically address details of the inductor coil; however, Huang et al teach an inductor coil that produces a rotating AMF. Huang et al establishes what is conventional in the art, that is, modulating pulses coupled with an inductor in the appropriate polarity for a resultant alternating current in the inductor [0029]. It would have been obvious to one of ordinary skill in the art at the time of invention, to include the configuration taught by Huang et al. in the system of Gray et al. in order to achieve expected results of generating an alternating current in an inductor.

5. Claims 5, 6 and 7 are rejected under 35 U.S.C 103(a) as being unpatentable over Gray et al. (US 6,167,313) in view of Itoh et al. (US 4,979,518) and Gruettner et al. (US 2005/0271745), as applied to claims 1 and 2, further in view of Mills (US 6,477,398).

Gray et al as appended by the thermal probe of Itoh et al includes all features of the invention as substantially claimed but does not specifically include subjecting the patient to a magnetic field in the context of imaging the patient; however, Mills teaches thermal therapy in conjunction with MR imaging (abstract; also col. 18, lines 8-15). It would have been obvious to one of ordinary skill in the pertinent art at the time of invention to modify the system of Gray et al (as used with the probe of Itoh et al) to include monitoring the patient with MR imaging during treatment to visualize the area of pathological tissue as well as the progress of treatment.

6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gray et al. (US 6,167,313) in view of Itoh et al. (US 4,979,518) and Gruettner et al. (US 2005/0271745), as applied to claim 1, further in view of Handy et al. (US 2003/0032995, now US 6,997,863).

While Gray et al disclose use of antibodies in a targeted thermal therapy system, it is not specifically disclosed that one or more ligands are used; however, Handy et al establishes that it is desirous to use magnetic particles in an injection that attach to a target-specific ligand (abstract; also [0008], [0009]). It would have been obvious to one of ordinary skill in the relevant art at the time of invention to include a ligand for binding to a targeted site as taught by Handy et al [0009].

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda L. Lauritzen whose telephone number is (571)272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amanda L. Lauritzen/
Examiner, Art Unit 3737

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit 3737